UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	)	MDL No. 1456
	)	Civil Action No. 01-12257-PBS
	)	Judge Patti B. Saris
THIS DOCUMENT RELATES TO 01-CV-12257-PBS AND 01-CV-339	)	

TRIAL OF CLASS 2 AND 3 CLAIMS

AFFIDAVIT OF TIMOTHY S. SNAIL, PH.D.
SUBMITTED AS DIRECT TESTIMONY IN CASE-IN-CHIEF
OF BRISTOL-MYERS SQUIBB CO. AND
ONCOLOGY THERAPEUTICS NETWORK CORP.
IN THE TRIAL OF CLASS 2 AND 3 CLAIMS

STATE OF MASSACHUSETTS)
)
COUNTY OF SUFFOLK) ss:

TIMOTHY S. SNAIL, being duly sworn, deposes and says:

1. I am a Principal at CRA International ("CRA"), an economics and management consulting firm. I received my B.S. from the University of Chicago in mathematics and my Ph.D. from the University of California, Berkeley, in economics. I submit this affidavit as direct testimony in the case-in-chief of Bristol-Myers Squibb Co. ("BMS") and Oncology Therapeutics Network Corp. ("OTN").

2. I have been asked by counsel for BMS and OTN to explain how CRA conducted financial analyses of records from Dr. Linda A. Haegele's office-based oncology practice to support her merits report and trial affidavit.[1]

3. I supervised the day-to-day work of the CRA team that conducted analysis of Dr. Haegele's practice economics. I was supported primarily by the following CRA staff: Kurt Lavetti (B.S. in economics) reviewed Dr. Haegele's hardcopy and electronic records, summarized the information using computer programs and spreadsheets, and constructed exhibits that summarized our analyses of billings, reimbursements, revenues, and expenses. Barbara Silk (B.A. in economics), and Stephan Seabrook (B.A. in economics), assisted in reviewing billing and reimbursement records and summarized the records using spreadsheets. Timothy Day, a certified public accountant with a Ph.D. in economics, assisted team members with financial accounting issues.

4. CRA receives compensation for my time at the rate of $425 per hour. Neither CRA nor I have any financial interest in the outcome of this litigation.

5. My affidavit is organized as follows. Section I describes the data sources that the team collected to conduct financial analyses of Dr. Haegele's practice economics. Section II discusses our analysis of the billing and reimbursement records of Dr. Haegele's office-based oncology practice. Finally, Section III explains our analysis of the revenues and expenses of Dr. Haegele's practice.

I. Data Sources Gathered for Analysis of Dr. Haegele's Practice Economics

6. Members of the CRA team visited Dr. Haegele's office in Philadelphia, Pennsylvania from October 25 – 27, 2005 and again on December 5, 2005 to meet with Dr. Haegele and her staff. During these visits, CRA collected Dr. Haegele's financial records to conduct economic analyses of her office practice. After

[1] Affidavit of Linda A. Haegele, M.D., Submitted as Direct Testimony in the Case-in-Chief of Bristol-Myers Squibb Co. and Oncology Therapeutics Network Corp. in the Trial of Class 2 and 3 Claims ("Haegele Affidavit").

reviewing the financial records, the team entered information from the hardcopy records into spreadsheets.[2]

7. In the course of our work, CRA had conversations with Dr. Haegele and her staff regarding their business practices and recordkeeping, the interpretation of insurance reimbursement forms and other records, and patterns observed in the records.

8. CRA gathered various financial records of Dr. Haegele's practice from 2002 to 2005. Because the hardcopy records relating to insurance reimbursements were too voluminous to review fully during the site visits, CRA made photocopies of the records. CRA also gathered hardcopy records of income tax returns, electronic copies of profit and loss statements maintained in QuickBooks by Dr. Haegele's office, and facsimiles of office records relating to Amgen drug rebates.

9. In addition, counsel provided CRA with electronic records of Dr. Haegele's purchases of drugs and other supplies from defendant OTN[3] from 2002 to 2005. To analyze the practice's drug costs and reimbursements, CRA also referred to the American Medical Association's HCPCS 2006 publication for standard dosages associated with specific drug-related procedure codes (e.g., J-Codes).

10. All hardcopy and electronic information used by CRA in producing exhibits for Dr. Haegele's report and trial affidavit were provided to counsel at the conclusion of our analysis.

II. Analysis of Billing and Reimbursement

11. This section explains the general characteristics of the billing and reimbursement information provided by Dr. Haegele's office to CRA, and how we recorded and analyzed that information.

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[2] The information collected from Dr. Haegele's records is described briefly in the following paragraphs, and in detail in the sections entitled "Analysis of Billing and Reimbursement" and "Analysis of Revenues and Expenses," below.

[3] OTN is the specialty distributor from which Dr. Haegele's office purchased drugs and supplies.

A. Explanation of Benefits Forms

12. When third-party payors, such as private health insurance plans and Medicare, send reimbursement to a physician for a previously filed health insurance claim, they include an Explanation of Benefits form ("EOB") to explain why payments are made or denied for each claim. Although the format of the EOBs varies across payors and some forms include more information than others, there are generally several sections that contain pertinent information: the letterhead at the top of the EOB form; procedure lines in the middle; and a bottom section of totals and notes. The payor name is usually provided in the letterhead. The middle of the form generally lists at least several different types of information for each procedure, grouped by patient visit: date, procedure code, quantity, secondary insurers, allowed amount, and amount paid. After the procedure lines, there may be totals reflecting amounts in aggregate for all patient visits on the claim. Each third-party payor has a different set of standardized notes that describe the reasons for payments (or denial of payments) and/or the status of the claim. These notes generally appear either in full in the vicinity of the applicable procedure line, or in abbreviated form near the procedure line with a more complete description at the end of the EOB.[4]

13. CRA transferred information from the EOBs received by Dr. Haegele's office from 2002 to 2005 into tabular format, wherein each line described a single procedure for a specific patient visit. Information that applied to all procedures on the claim (e.g., payor name) was entered on each line of the claim. EOBs were the principal source of information used in CRA's analysis of billing and reimbursement, which is described in the next section. What follows in this section is a description of how the information was recorded by CRA for the purposes of its analysis.

14. Payor: Payor names were initially recorded as written on the letterhead of the EOBs, and were later standardized after typographical errors were corrected. Dr. Haegele's Medicare claims were usually paid by a third-party carrier named HGS

[4] EOBs list other information that was not used in CRA's analysis, such as names and identifying numbers for patients and providers.

Administrator.[5] Most of the other information we transferred from the EOB form appeared in the procedure lines and is described in the following paragraphs.

15. Date: EOBs frequently list several dates, including the date of service (i.e., the date on which each listed procedure was performed) and the date on which the reimbursement check was issued by the third-party payor. The date of service was the date used in our financial analyses.[6]

16. Procedures Codes: EOBs generally list the procedures for which payment is being made, with the procedures grouped together for each patient visit. Thus, a twenty-minute patient visit that included an injection of a drug may involve two or more procedure codes (one for the visit fee, and another for the injection). The visit fee (or any other service) is identified by a CPT code (as defined by the American Medical Association), which is usually a 5-digit numeric code although it may be longer.[7] Any covered drug administered during the visit is identified by a HCPCS Level-II code such as a J-Code (as defined by the Centers for Medicare and Medicaid Services, or "CMS"), which is usually a 5-digit code beginning with a "J" and is followed by four numeric digits, although it may be longer. A drug or related procedure may be identified by a temporary HCPCS Level II code that begins with a letter other than "J."[8] It is not unusual for a claim to have ten to twenty associated procedure codes for a single patient visit. On occasion a claim listed reimbursement amounts that were not assigned to individual procedure codes; although the procedure code itself was missing, we recorded the dollar amounts and

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[5] For other examples of the payors listed in the EOBs, see the Haegele Affidavit, ¶ 44.

[6] When the date of service for the procedure was missing or illegible (primarily in 2002), it was estimated from the posting date, the date the EOB was posted in the office's accounting system.

[7] The CPT codes may be followed by modifiers, such as '-25', '-59', and '-WT'.

[8] For example, a temporary code commonly used by Dr. Haegele's practice is Q0136 (epoetin alfa, non-ESRD, per 1000 units). See Healthcare Common Procedure Coding System (HCPCS) Level II Coding Procedures, Rev. November 30, 2005, p. 5, available at http://www.cms.hhs.gov/MedHCPCSGenInfo/Downloads/LevelIICodingProcedures113005.pdf.

other information.[9] We later classified procedures as relating to drugs, services, the 2005 Oncology Demonstration Project,[10] and not otherwise classified.[11]

17. Quantity: The quantity is the number of "units" associated with a procedure code. If, for example, a patient was administered an injection equivalent to ten standard "doses" of a drug (where the standard dosage is defined for the particular J-Code), the claim would have one instance of the J-Code specifying ten units.

18. Supplemental Insurance: Medicare Part B pays for 80 percent of the charges associated with covered services and drugs, while Medicare beneficiaries are responsible for the remaining 20 percent. Some beneficiaries pay this amount out-of-pocket, while others subscribe to a Medicare supplemental health insurance plan ("Medigap plan") that may cover part of the amount, such as the Medicare coinsurance, co-payments ("co-pays"), and deductibles. If an EOB indicates that payment for a procedure code was made by two different third-party payors, in principle both could be private payors or one could be Medicare and the other a Medigap plan. For Dr. Haegele's EOBs, the only dual payors were Medicare and Medigap.[12] Where procedures were paid for by a Medigap plan, they were noted in CRA's tabular representation of the EOBs.

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[9] This occurred only for some supplemental insurance plan EOBs; it affected only the classification of revenues, not the net income. Since both the Medicare EOB and supplemental insurance plan EOB for a particular procedure refer to the same allowed amount, the supplemental insurance plan EOBs were later excluded from our analyses of allowed amounts to avoid potential double counting.

[10] CMS initiated the 2005 Demonstration of Improved Quality of Care for Cancer Patients Undergoing Chemotherapy ("Oncology Demonstration Project"), a 1-year project that partly offset the reduced reimbursements for Part B drugs under the Medicare Modernization Act of 2003. See "Demonstration of Improved Quality of Care for Cancer Patients Undergoing Chemotherapy," CMS, Nov. 1, 2004, available at http://www.cms.hhs.gov/apps/media/press/release.asp?Counter=1245; and Medicare Program, Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2005, Final Rule, 69 Fed. Reg. 66308 (November 15, 2004), available at http://www.cms.hhs.gov/quarterlyproviderupdates/downloads/CMS1429FC_1.PDF and http://www.cms.hhs.gov/quarterlyproviderupdates/downloads/CMS1429FC_2.PDF.

[11] In the income statements produced by CRA, revenues for procedure codes that could not be classified as relating to drugs or services were included in the category "Other Amounts Paid."

[12] This was apparent from the third-party payor names and amounts covered by Medicare listed on each EOB. Dr. Haegele's office confirmed that the only EOBs for which their patients had multiple payors were claims involving Medicare supplemental insurance plans.

19. Allowed Amount: The allowed amount is the dollar amount that a payor agrees to pay the physician for a particular procedure code (usually including the total payments to the provider as well as payments that are the responsibility of the patient and other payors). The allowed amount may differ from the amount billed by the provider ("billed amount"). The allowed amount may be explicitly identified on the EOB or calculated as a list price less a negotiated discount off of the list price. The amount paid by the payor listed on the EOB is less than or equal to the allowed amount.

20. Member Responsibility Amount: The member is responsible for a co-payment or coinsurance payment and the third-party payor pays the remaining balance. In some instances, the payor does not cover the charges associated with a procedure code. In such cases, the member is responsible for the entire billed amount.

21. Amount Paid: The amount paid is the portion of the allowed amount that is paid for by the third-party payor.

22. Total Claim Amount: The total claim amount equals the amount of the reimbursement check accompanying the EOB. In the tabular representation of the EOB, we entered the total claim amount at the end of the claim.

23. After CRA transferred information from the hardcopy EOBs into electronic tabular format, the data were checked for completeness and accuracy. We then analyzed billing and reimbursement of Dr. Haegele's practice as described in the next section.

B. Analysis of Billing and Reimbursement

24. CRA's analysis of billing and reimbursement included calculations of the amounts paid to Dr. Haegele's practice by each third-party payor for each procedure code from 2002 to 2005.[13] We observed variation in reimbursement amounts for specific procedures within and across payors, and at times even within the same time period.

[13] For example, we calculated the reimbursement amount for each line of the EOB and the average reimbursement amount for each combination of third-party payor, drug-related procedure code, and year.

The reimbursement variation across payors was mostly likely driven by differences in their reimbursement rates. The reimbursement variation within each payor was likely the result of the different reimbursement rates that each payor sets for its various health plans (e.g., HMO, PPO). The reimbursement differences within payors may also be driven by the ways in which reimbursement amounts were reported on the EOBs. For example, some EOBs contained notes indicating that reimbursement amounts included adjustments such as interest for late payments; thus, the amounts were not necessarily the standard reimbursement rates of payors. Due to the nature of the observed variation in reimbursement amounts, we determined that the most frequently-occurring values of the reimbursement amounts in a given period were more likely to accurately reflect payors' standard reimbursement rates than would the average or the median of the reimbursement amounts.

25. We discussed this finding and others based on the EOBs with Dr. Haegele, and provided written materials consisting primarily of the tabular representation of the EOBs and summary statistics. Dr. Haegele made the final determination of the reimbursement rates paid by payor, procedure, and year reported in section V ("Billing and Reimbursement for Office-Based Oncology") of her trial affidavit.[14]

26. The dates of service listed on the EOB were used to determine the year of the reimbursement since the analyses for the Haegele Affidavit were intended to reflect accounting on an accrual basis.[15]

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[14] See the table of "Reimbursement Amount for Level V Initial Office Visit," Haegele Affidavit, ¶ 47 at p. 21 (DX 1220, attached hereto at Attachment A); the table of "Reimbursement Amount for Level V Established Patient Visit," Haegele Affidavit, ¶ 47 at p. 21 (DX 1221, attached hereto at Attachment B); the table of "Reimbursement Amount for Blood Count Lab Work," Haegele Affidavit, ¶ 48 at p. 22 (DX 1222, attached hereto at Attachment C); the table of reimbursement amounts for drug administration by payor, 2002–2003, Haegele Affidavit, ¶ 49 at p. 24 (DX 1223, attached hereto at Attachment D); and the table of reimbursement amounts for drug administration by payor, 2004–2005, Haegele Affidavit, ¶ 49 at p. 25 (DX 1224, attached hereto at Attachment E).

[15] Accounting on an accrual basis recognizes revenues when they are earned and expenses in the period in which related revenue is recognized; cash basis accounting recognizes revenues when cash is received and expenses when cash is paid. See the section "Analysis of Income Statements" for a discussion of accounting on an accrual versus cash basis.

III. Analysis of Revenues and Expenses

27. This section explains the general characteristics of the revenue and expense information provided by Dr. Haegele's office to CRA, and how we recorded and analyzed the information. The principal sources of information were the OTN data and QuickBooks accounting records, from which we determined the revenues and expenses of Dr. Haegele's practice, as described below. The findings of our analyses were primarily presented in the form of income statements, which are described in a later section.

A. OTN Data

28. Dr. Haegele's practice purchased drugs and medical supplies from OTN from 2002 to 2005.[16] The records of Dr. Haegele's purchases from OTN were provided to CRA in an Excel spreadsheet wherein each row specified the following fields: account number, account name, NDC code, description, dose, dose unit, invoice number, invoice date, invoice quantity, and cost. One invoice may consist of one or more rows of information. The OTN spreadsheet contains only one account number ("103263") and account name ("Physician Oncology, LTD"), identifying Dr. Haegele's practice. The remaining fields are as follows.

29. NDC Code: The National Drug Code ("NDC") listed with the Food and Drug Administration ("FDA") identifies the characteristics of a drug product, including the labeler (which may be the manufacturer), trade name, active ingredients (often the generic drug name), dosage form, administration method, strength, units, package size, and package type. The NDC codes found in the OTN data were later linked to J-Codes by reference to the CMS crosswalk.[17] For entries other than drug purchases (e.g., supplies, returns, discounts, credits, or rebates), the OTN data contain other types of identifying codes in the NDC column.

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[16] Haegele Affidavit, ¶ 32.

[17] "October 2005, NDC - HCPCS Crosswalk for Medicare Part B Drugs," available at http://www.cms.hhs.gov/McrPartBDrugAvgSalesPrice/02a_2005aspfiles.asp.

30. Description: The description field describes the drug (e.g., the chemical compound name, strength, and administration method), supply (e.g., catheters, needles, gloves), or other type of transaction (e.g., return, credit, or rebate).

31. Dose and Dose Unit: The dose (e.g., 150) and dose unit (e.g., milligram ("mg")) for each drug is listed in these fields. For items other than drugs, these fields were blank.

32. Invoice Number, Date, Quantity, and Cost: These fields list the OTN invoice number, invoice date, the quantity billed ("invoice quantity"), and the invoice amount in dollars ("cost").

B. QuickBooks Data

33. Dr. Haegele's practice uses QuickBooks, a commercially available software package, to track its revenues and expenses. Two types of QuickBooks data were provided to CRA in the form of spreadsheets: (1) detailed profit and loss information, and (2) summarized profit and loss information. The detailed information includes: an aggregate revenue or expense category (e.g., "Income" or "Expense"); a more detailed revenue or expense category (e.g., "Fee Income", "Medical Supplies"); the type of transaction (e.g., "Deposit", "Bill"); date; reference number; a name or description (e.g., "Commonwealth of PA", "Co-Pays"); a memo (e.g., "Aetna", "cash"); the "split" (e.g., "Accounts Payable", "Depreciation"); the dollar amount; and the dollar balance. The summarized profit and loss information contains only the following information: an aggregate and a more detailed revenue or expense category, and a dollar amount reflecting activity over the entire year. We primarily used the detailed profit and loss information.

34. Although both the QuickBooks data and hardcopy invoices contain information on expenses, the QuickBooks data were more complete.[18] Thus, our analyses of expenses did not rely on hardcopy invoices.

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[18] This is consistent with Dr. Haegele's conclusion; see Haegele Affidavit, ¶ 54.

35. Although both the OTN and QuickBooks data sources contain information on drug purchases, the OTN data were more comprehensive.[19] The other consideration in choosing between these data sources was the accounting basis under which the records were prepared. The QuickBooks data were intended to facilitate the filing of tax returns and thus reflect accounting on a cash basis, while the OTN data closely resemble accounting on an accrual basis. Thus, our analyses of drug purchase amounts were derived from the OTN data.

C. Revenues

36. Revenues were calculated from the EOBs by aggregating the amounts paid by payors into groups classified as procedures relating to drugs, services, the Oncology Demonstration Project,[20] or "other" amounts. The EOBs were also use to calculate the amounts designated as due from patients (e.g., co-pays, coinsurance).

37. Uncollected patient obligations were calculated from a combination of the EOBs and QuickBooks data as the amounts due under insurance plans and programs less the payments received from payors and patients.[21] Note that when an insurer does not cover a procedure, the patient is responsible for the entire billed amount rather than the allowed amount.

D. Expenses

38. Information relating to Dr. Haegele's practice expenses was derived from several sources. Expenses associated with purchases of prescription drugs and medical supplies were derived from the OTN data, as were rebates and discounts associated with OTN purchases. We also incorporated information on rebates paid by Amgen for Dr. Haegele's drug purchases, which were not included in the OTN data. Dr. Haegele's salary (i.e., "physician's salary" in income statement analyses) was

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[19] This is consistent with Dr. Haegele's conclusion; see Haegele Affidavit, ¶ 54.

[20] The category "Oncology Demonstration Project" includes payments from third-party payors (such as Medigap) for services provided under the Oncology Demonstration Project.

[21] See the 'Bad Debt" tab in the spreadsheet named "Exhibits 1, 2 – Income Statement.xls" included in the supporting materials to the Haegele Affidavit (DX 1228, attached hereto at Attachment F).

derived from wage and tax statements (i.e., W-2 forms) and payroll records. All other types of expenses were derived from the QuickBooks data (e.g., office supplies, payroll expenses and payroll taxes excluding physician's salary, employee health insurance, and rent).

E. Analysis of Income Statements

39. CRA summarized Dr. Haegele's practice revenues and expenses into income statements for the years 2002 – 2005 on an accrual basis using the dates of service.[22] While some of the underlying data sources were not prepared purely on an accrual basis, Dr. Haegele's rapid drug inventory turnover and relatively low cash expenditures on non-medical supplies make these records a close approximation to accounting on an accrual basis. Had the income statements been prepared on a cash basis, the results would have exhibited unusual patterns over time reflecting delays in bookkeeping and lags between the initiation of transactions and cash receipts and payments.[23]

40. Two income statements were prepared, both covering all sources of revenues and expenses: one presents revenues for drugs and services on a consolidated basis (Exhibit 1),[24] while the other separates drug and services revenues (Exhibit 2).[25] Records for the last calendar quarter of 2005 were not complete at the time CRA performed its work. Thus, information for the first three quarters of 2005 was annualized to facilitate comparisons in the aggregate to earlier years for which complete information was available. Note that the net income listed near the

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[22] For purchases of drugs and medical supplies, an invoice date was available in OTN data. Since Dr. Haegele usually maintains no more than one week of inventory for drugs and medical supplies (see Haegele Affidavit, ¶ 32), the invoice date was within the same year as the service date for the vast majority of the purchases.

[23] In fact, this most certainly occurred in 2003 when Dr. Haegele had an inexperienced biller; see Haegele Affidavit, ¶ 61. We observed unusually long lags between the dates of service and reimbursement payments (as well as posting into QuickBooks) in 2003.

[24] See Haegele Affidavit, Exhibit 1 at ¶ 57, p. 32 (DX 1225, attached hereto at Attachment G).

[25] See Haegele Affidavit, Exhibit 2 at ¶ 64, p. 36 (DX 1226, attached hereto at Attachment H).

bottom of each income statement reflects the net income of the practice without considering the cost of Dr. Haegele's salary.[26]

41. Exhibit 2 reports drug revenues and services revenues separately, and calculates the operating profit from drugs and operating profit from services by considering the revenues and costs for each activity. Operating profits from drugs are the Medicare and private payors' reimbursements for drugs plus patients' payments for drugs less the net costs of drug purchases and bad debt in the form of uncollected patients' drug payments.[27] Operating profits from services are the Medicare and private payors' reimbursements for services (i.e., office visits, lab work and drug administration) plus patients' payments for services less all non-drug expenses (i.e., medical supplies, office supplies, staff payroll expenses, rent, and other expenses).[28]

F. Analysis of Medicare Drug Margins

42. CRA examined the margins from individual drugs covered by Medicare in 2004 and 2005 (Q1–Q3), a period when Medicare and many private payors were implementing substantial changes to drug and services reimbursements. To calculate the drug margins, we subtracted the net cost per billing unit (i.e., Dr. Haegele's net costs of purchasing a drug divided by the billing unit associated with the J-Code) from the Medicare reimbursement amount (see Exhibit 3).[29] This analysis used a subset of the sources of information used for the income statements, focusing on drug revenues and expenses.

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[26] Losses due to denial of drug coverage by third-party payors are implicitly recorded as "OTN Drug Purchases" without offsetting revenues; see Haegele Affidavit, ¶ 58. Losses due to uncovered practice expenses are implicitly recorded as, for example, a portion of "Payroll and Payroll Taxes excluding physician's salary" without offsetting revenues; see Haegele Affidavit, ¶¶ 31–32, 35, 37–39, 41.

[27] See Haegele Affidavit, ¶ 63.

[28] See Haegele Affidavit, ¶ 64.

[29] See Haegele Affidavit, ¶ 69 at p. 38 (DX 1227, attached hereto at Attachment I).

Timothy S. Snail

Sworn to before me this
16th day of November 2006

Notary Public

CATHERINE M. JOYCE
Notary Public
Commonwealth of Massachusetts
My Commission Expires
April 3, 2009